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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ralf Ehricht

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EXAMINER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/038,284	Applicant(s) EHRICHT ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 May 2010 has been entered.

Status of the Claims

2. This action is in response to papers filed 3 May 2010 in which claim 51 was amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 2 November 2009 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 51-67 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 51, 58-59, 62, 64 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Schembri (U.S. Patent No. 6,162,400, filed 12 August 1998).

Regarding Claim 51, Schembri teach a device comprising a chamber support (#65) having an optically permeable first surface (#67) facing the reaction chamber (#5), a chamber body (#3) sealingly and unreleasably placed on the chamber body (Column 8, lines 40-42), the body comprising a recess having an edge (#63) configured to support a chip on the support, an inlet (#11) and fluid drain (#15) providing fluid communication between the external environment and the reaction chamber. Schembri further teaches a rigid and optically permeable chip (#13) sealingly supported by the recess (via attachment to the inner surface of the support, Column 8, lines 52-55) and having a surface facing the reaction chamber and having an array of multiple different polynucleotide probes (Column 8, lines 25-64 and Fig. 6).

Regarding Claim 58, Schembri teaches the device wherein the support (Column 8, lines 39-40) and chamber body (Column 5, lines 11-15) consist of one of glass, synthetic material and optically permeable material.

Regarding Claim 59, Schembri teaches the device wherein the support consists of thermally conductive material e.g. glass (Column 8, lines 39-40)

Regarding Claim 62, Schembri teaches the device wherein the chamber body includes an inlet and outlet spatially separated from each other an inlet (#11) and fluid drain (#15)(Fig. 6).

Regarding Claim 64, Schembri teaches the device wherein the chamber body is sealingly connected to the chamber support by adhesive or weld connection (Column 8, lines 40-42)

Regarding Claim 66, Schembri teaches the device is adapted to allow for optical detection (#69, Fig. 6, Column 8, lines 34-35).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 51-55 and 58-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al (U.S. Patent No. 6,093,370, filed 10 June 1999) in view of Stapleton et al (U.S. Patent No. 5,922,604, filed 5 June 1997).

Regarding Claim 51, Yashuda teaches a device for amplification and detection of nucleic acids (Fig. 6 and side view Fig. 8) the device comprising a chamber support having an optically permeable first surface (i.e. cover plate, #721) facing the reaction chamber, a chamber body (lower plate, #722) placed on the chamber body (Fig. 6 & 8), the body comprising a recess having an edge configured to support a chip (#1) on the

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support (see side view, Fig. 8), an inlet (#711-713) providing communication between the external environment and the reaction chamber. Yashuda further teaches a rigid and optically permeable chip (#1) supported by the recess (see cut-away view Fig. 6) and having a surface facing the reaction chamber and having an array of multiple different polynucleotide probes (Column 9, lines 1-40 and Fig. 6 & 8).

Yashuda is silent regarding sealing of the device, however amplification chambers sealed via adhesive were well known and routinely practiced in the art at the time the invention was made as taught by Stapleton (Column 5, lines 44-55).

Stapleton et al teach a similar device for PCR comprising a chamber support having an optically permeable surface (glass slide, 14) a chamber body sealingly placed to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), wherein the cavity contains an array of nucleic acid probes immobilization (Column 5, lines 40-44). Stapleton further teaches the arrayed probes provides a large surface areas to volume ratio reduces the amount of reagents required while increasing the number of reactions performed and facilitates temperature cycling required for PCR (Column 4, lines 22-36). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the adhesive of Stapleton to the PCR chamber of Yashuda. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of preventing evaporation and loss of reagents as desired in the art (Stapleton, Column 1, lines 55-59).

Regarding Claim 52, Yashuda teaches the device further comprising temperature adjustment means connected to the chamber support (Column 9, line 27-34).

Regarding Claim 53, Yashuda teaches the temperature adjustment means connected to a bottom side of chamber facing the chamber body (Column 9, line 27-34, Fig. 6 and 8)

Regarding Claim 54, Yashuda teaches the device wherein the transparent upper plate is not obscured by the temperature adjustment means such that the transparency of the chip is unaffected (Column 9, lines 1-40).

Regarding Claim 55, Yashuda teaches the device wherein the heating elements (#32, 34, 35) are micro-structured (e.g. embedded in the substrate, Column 9, lines 27-34 and Fig. 6).

Regarding Claim 58, Yashuda teaches the device wherein the support comprises optically permeable material (i.e. cover plate, Column 9, lines 12-13) and Stapleton teaches the similar device wherein the support and chamber body consist of one of glass and/or synthetic material (Column 5, lines 40-50).

Regarding Claim 59, Yashuda teaches the device wherein the support consists of thermally conductive material i.e. for conducting heat from elements (#32, 34, 35) (Column 9, lines 27-40).

Regarding Claim 60, Yashuda teaches the chip comprises glass (Column 13, lines 52-55) and Stapleton teaches the chip comprises glass (Column 6, lines 1-2).

Regarding Claim 61, Yashuda does not teach a conical shape.

However, the courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA

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1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Furthermore, Stapleton teaches the similar device further comprising an optically permeable conical recess in the detection area (inverted cone #28, Column 9, lines 50-59).

Regarding Claim 62, Yashuda teaches the device wherein the chamber body includes an inlet and outlet spatially separated from each other (#711-713) (Fig. 6).

Regarding Claim 63, Yashuda is silent regarding a gas reservoir. However, Stapleton teaches the similar device wherein the spatially separate inlet (#20) and outlet (#30) are arranged unilaterally to the chip (Fig. 1) and separated by a gas reservoir (i.e. inflatable valve, Column 13, lines 26-40).

Regarding Claim 64, Yashuda is silent regarding a seal. However, Stapleton teaches the similar device having a chamber body sealingly placed via adhesive to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9),

Regarding Claim 65, Yashuda teaches the device wherein the nucleic acids are immobilized through spacers (#305)(Fig. 16).

Regarding Claims 66-67, Yashuda teaches the device is adapted to allow for optical detection (#15, Fig. 6, Column 9, lines 36-40).

The instant specification defines a transparent chamber for optical detection (paragraph spanning pages 20-21) but does not define any additional structural

requirement for characterization of silver precipitation. Hence, the transparent chamber allowing optical detection as taught by Yashuda is encompassed by the claim.

7. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al (U.S. Patent No. 6,093,370, filed 10 June 1999) in view of Stapleton et al (U.S. Patent No. 5,922,604, filed 5 June 1997) as applied to Claim 51 above and further in view of McBride et al (U.S. Patent No. 6,296,752, filed 4 June 1999) as defined by Academic Press Dictionary of Science and Technology (Academic Press, San Diego, 1992, page 1768)

Regarding Claims 56 and 57, Yashuda further teaches the chamber comprises opposing electrodes (#751 & 754) for electro-osmotic flow (Fig. 7). And Stapleton et al teach the device comprising automated fluidic movement (Column 9, lines 9-36 and Column 14, lines 25-35). However, Yashuda and Stapleton are silent regarding a quadrupole system comprising electrodes of gold-titanium.

However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16) wherein their electrode device comprises multiple electrodes providing a distribution of magnetic poles (Column 3, lines 34-55). Furthermore, Academic Press Dictionary of Science and Technology defines a distribution of magnetic poles as a quadrupole. Therefore, the multiple electrode

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device of McBride et al is a quadrupole system as defined by the Academic Press Dictionary.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the multiple gold-titanium electrodes of McBride et al to the electrodes of Stapleton et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
Art Unit 1634

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